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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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WILLIAM L. WARREN
SUTHERLAND ASBILL & BRENNAN LLP
999 PEACHTREE STREET, NE
ATLANTA, GA 30309-3996

EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,067	WEINER ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,21-24 and 26-32* is/are pending in the application.

4a) Of the above claim(s) *21-24,26 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4, 27, 29-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 4, 21-24, and 26-27 have been amended, claims 3, 5-20 and 25 have been canceled and claims 29-32 have been added in the amendment of 13 November 2006. Claims 21-24, 26 and 28 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 05 May 2006. Claims 1, 2, 4, 27 and 29-32 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 13 November 2006 have been fully considered but they are not deemed to be persuasive.

Response to Amendment

It is noted that Applicant's statement that "Enabling support for the amendments can be found in the application as filed" is not sufficient for pointing out support for the new claim limitations. With respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims. See MPEP § 714.02 and § 2163.06 ("Applicant should * * * specifically point out the support for any amendments made to the disclosure."); and MPEP § 2163.04 ("If

applicant amends the claims and points out where and/or how the originally filed disclosure supports the amendment(s), and the examiner finds that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of the filing of the application, the examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.").

Information Disclosure Statement

Applicant filed an IDS (11/13/06). However, there is no information listed on the IDS. There are no references and there is no application information. Therefore, there is nothing to consider – the form has been marked through.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 30 and 32 recite the limitation "at least 95% identical to the sequence of SEQ ID NO:24". However, this limitation does not find support in the instant specification as filed, and therefore is considered new matter.

Claims 1-2 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide having the amino acid sequence of SEQ ID NO:24, or an N-terminal fragment of growth hormone consisting of approximately 135 amino acids, does not reasonably provide enablement for a genus of anti-angiogenic peptides substantially identical to 133 consecutive amino acids of the N-terminal end of human growth hormone. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification indicates that a polypeptide corresponding to the 16 kD N-terminal fragment of human growth hormone (-1 Met to Pro133 – SEQ ID NO:24), has the property of inhibiting angiogenesis (e.g. page 50 and 55-57), yet the claims encompass a vast genus of fragments and variants of this peptide. The specification provides no examples which support the breadth of the claims, which encompasses molecules which are "substantially identical" and which are anti-angiogenic. The specification has provided no guidance as to what portion of the 16kD human growth hormone is responsible for the biological activity of being anti-angiogenic. The specification has provided no examples of mutations (other than mutation of Cys53 to Ser53) which have the required biological activity. The 16kD human growth hormone

differs in biological activity from the full length human growth hormone, therefore, structurally, there is a difference which provides for this activity. Without the knowledge of what portions of the 16KD human growth hormone are responsible and critical for this activity, the skilled artisan would not be able to make peptides which are "substantially identical" to the N-terminal end of human growth hormone which have the required anti-angiogenic activity of the claims. Further, the skilled artisan would expect that the majority of such fragments would not work as claimed. Khurana et al. (Endocrinology 140: 4127-4132, 1999) teach that peptides of the 16kD fragment of prolactin missing the first 53 amino terminal residues lacked anti-angiogenesis activity (see for example the middle paragraph of the first column of page 4131). Prolactin and growth hormone belong to a common protein family and the 16kD fragment of prolactin and the 16kD fragment of growth hormone both possess anti-angiogenic activity. Based on the structural and functional relationship between these two proteins, one of ordinary skill in the art might expect to find a similar loss of anti-angiogenic activity in the 16kD human growth hormone as well. The specification has not provided guidance as to any correlation between the structure of the fragments and the desired function of the fragments, such that the skilled artisan could make a peptide which differed from that of the 16kD human growth hormone or the peptide of SEQ ID NO:24 and expect the required biological activity of the claims. The specification has failed to provide adequate guidance as to which of the multitude of fragments and variants encompassed by the claims such that the molecules might have the desired activity.

Therefore, due to the large quantity of experimentation necessary to generate the tremendous multitude of peptide fragments recited in the claims and screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the requirement for a significant portion of the N-terminus of the 16kD protein for activity, and the breadth of the claims, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4, 27, 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites an "isolated anti-angiogenic peptide substantially identical to 133 consecutive amino acids of the N-terminal end of growth hormone". However, the metes and bounds of "substantially" cannot be determined. "Substantially" is a term of degree which has not been defined. Therefore, without knowing how much is considered "substantial", one of ordinary skill in the art would not be able to determine the metes and bounds of the claims. Claims 2, 4, 27 and 29-32 are also indefinite for depending from an indefinite claim.

Claim 27 recites "an isolated peptide as shown in SEQ ID NO:24". However, the metes and bounds of the phrase "shown in" are not clear. SEQ ID NO:24 is an amino acid sequence, which can represent the primary amino acid sequence of a peptide. However, it cannot actively "show" anything. The peptide can have the amino acid sequence of SEQ ID NO:24 (see language of claim 24), it can comprise the amino acid sequence of SEQ ID NO:24, it can consist of the amino acid sequence of SEQ ID NO:24, but the recitation of "shown in" is unclear and indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 27, and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Regan et al. (Proc. Nat. Acad. Sci. USA 72(5): 1684-1686, 1975).

Regan et al. teach human growth hormone which has been digested with plasmin and the result of digestion with plasmin is a human growth hormone having the amino acid structure of N-terminal amino acids 1-134 (see Regan et al. at column 1, paragraph 1). Regan et al. teach the isolation of this growth hormone molecule (Figure 1 at page 1685). Regan et al. is silent as to the anti-angiogenic activity of the peptide,

however, this is a property that would have been possessed by the peptide of Regan et al., and therefore, the claims are anticipated by the prior art.

Applicant has argued that the claims now recited "isolated" and that the specification defines a substantially purified or isolated protein as comprising more than 80% of all the molecular species presenting the preparation. However, the single band represented in Figure 1 appears to meet this definition of isolated, and therefore, anticipates the claims.

Allowable Subject Matter

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud